NEWS RELEASE

BioVie Announces Patent Issuance Covering Ascites Treatment with BIV201

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CARSON CITY, Nev., June 23, 2022 (GLOBE NEWSWIRE) -- **BioVie Inc.** (NASDAQ: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug therapies for the treatment of advanced liver disease and neurological and neurodegenerative disorders, today announced that a patent covering the use of terlipressin monotherapy to treat ascites patients who have not progressed to hepatorenal syndrome (“HRS”) has been issued by the U.S. Patent & Trademark Office. This action restores U.S. patent protection for BIV201 (continuous infusion terlipressin), which had previously been lost due to an Inter Partes Review (“IPR”) challenge to a related patent by another company.

“This newly-issued method of use patent, achieved through a continuation filing relating to our 2015 patent application, is expected to cover treatment with BIV201 in the U.S. until 2036. We are also pursuing overseas patent issuances,” said Cuong Do, chief executive officer of BioVie. “This new patent, together with our U.S. Orphan drug designation, global patent applications covering our novel liquid formulation, and a new patent application that the Company has not yet disclosed, is expected to provide critical long-term intellectual property protection.”

Ascites may occur when severe liver disease progresses to cirrhosis and the liver fails, leading to the accumulation of excessive fluid in the abdomen. Since no therapies are approved to treat ascites in the U.S., clinicians may resort to the off-label use of diuretic drugs. Although some patients may show a response, many become intolerant to or unresponsive to diuretics over time – developing a condition called refractory ascites. Refractory ascites affects 20,000 patients in the U.S. each year. When medications are ineffective patients suffering from refractory ascites may be forced to have their excessive abdominal fluid physically removed by a large bore needle guided through the skin into the abdomen in a procedure called paracentesis. While paracentesis may provide patients with some symptomatic relief, fluid cyclically reaccumulates since there is no change to underlying liver disease pathology. Consequently, patients often need to repeat paracentesis on a weekly to monthly basis to remove multiple liters of fluid each time. As the ascites condition worsens, many patients progress to develop more advanced ascites

complications such as hepatorenal syndrome, hepatic encephalopathy, gastro-intestinal bleeding, etc. Treatment goals when patients develop refractory ascites include the prevention of advanced ascites complications, as well as continued survival in hopes of qualifying for a liver transplant in time. Due to the disease severity and relative shortage of liver transplants, 50% mortality rate within 6-12 months is common for refractory ascites patients.

Multiple uncontrolled clinical studies, including the Phase 2a trial previously conducted by BioVie, have demonstrated that BIV201 appears to reduce ascites fluid build-up and may extend the period of time between required paracenteses. The Company is currently conducting a Phase 2b trial attempting to show that the reduction of ascites symptoms can lead to a reduction of advanced ascites complications such as HRS.

About Ascites and BIV201

Ascites is a common complication of advanced liver cirrhosis involving the accumulation of large volumes of fluid in the abdomen, often exceeding 5 liters, due to liver and kidney dysfunction. An estimated 20,000 Americans suffer from refractory ascites, which means that their ascites no longer responds to off-label diuretic therapy, or they cannot tolerate these drugs. The FDA has never approved a drug for treating ascites, and once patients reach the refractory stage the estimated one-year survival rate is only approximately 50% (Bureau et al. 2017). BIV201 is a continuous infusion of terlipressin, a drug used in over 40 countries to treat related complications of liver cirrhosis that is not available in the U.S. or Japan.

The Phase 2b trial is evaluating the efficacy of BIV201, which has an Orphan drug designation, in addition to standard-of-care ("SOC") compared to SOC alone for the treatment of refractory ascites in the home care setting. BIV201 is being administered using the Company's patent-pending liquid formulation of terlipressin in a prefilled syringe format as a continuous low dose infusion with a portable pump. The primary endpoints are the incidence of serious disease-related complications and the change in cumulative ascites fluid volume in the BIV201 treated group (20 patients) versus the control group (10 patients). If the results are positive, the Company plans to conduct a pivotal Phase 3 trial commencing in 2023. BioVie previously conducted a Phase 2a trial of BIV201 at a Veterans Administration hospital. The pharmacokinetics (PK) of terlipressin following continuous infusion generated in this study determined for the first time that administration of terlipressin as a low dose continuous infusion avoids high, potentially harmful, peak blood concentrations associated with intermittent IV bolus dosing (accepted for publication). The study also found that the drug was overall well tolerated and that it was feasible to administer terlipressin by continuous infusion in an outpatient setting.

About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative therapies to overcome unmet medical needs in chronic debilitating conditions. In liver disease, the Company's Orphan drug candidate BIV201 (continuous infusion terlipressin), with FDA Fast Track status, is being evaluated in a US Phase 2 study for the treatment of

refractory ascites due to liver cirrhosis with top-line results anticipated in early 2023. BIV201 is administered as a patent-pending liquid formulation. The active agent is approved in about 40 countries for related complications of advanced liver cirrhosis but is not available in the U.S. or Japan. In neurodegenerative disease, the Company's drug candidate NE3107 inhibits inflammatory activation of ERK and NFkB (e.g., TNF transcription) that leads to neuroinflammation and insulin resistance, but not their homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both are drivers of Alzheimer's and Parkinson's diseases. The Company is conducting a potentially pivotal Phase 3 randomized, double blind, placebo controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). An estimated six million Americans suffer from Alzheimer's. BioVie has initiated this study and is targeting primary completion in mid-2023. A Phase 2 study of NE3107 in Parkinson's disease is enrolling patients and expect to have topline data readout by mid-year 2022. NE3107 is patented in the United States, Australia, Canada, Europe, and South Korea. For more information, visit http://www.bioviepharma.com/.

Forward-Looking Statements

This press release contains forward-looking statements, which may be identified by words such as "expect," "look forward to," "anticipate" "intend," "plan," "believe," "seek," "estimate," "will," "project" or words of similar meaning. Although BioVie Inc. believes such forward-looking statements are based on reasonable assumptions, it can give no assurance that its expectations will be attained. Actual results may vary materially from those expressed or implied by the statements herein due to the Company's ability to successfully raise sufficient capital on reasonable terms or at all, available cash on hand and contractual and statutory limitations that could impair our ability to pay future dividends, our ability to complete our clinical trials and to obtain approval for our product candidates, to successfully defend potential future litigation, changes in local or national economic conditionsas well as various additional risks, many of which are now unknown and generally out of the Company's control, and which are detailed from time to time in reports filed by the Company with the SEC, including quarterly reports on Form 10-Q, reports on Form 8-K and annual reports on Form 10-K. BioVie Inc. does not undertake any duty to update any statements contained herein (including any forward-looking statements), except as required by law.

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